OCT 1 3 2000

K002467

Section 3
510(k) Summary for Coaliza Protein S-Free
(Summary of Safety and Effectiveness)

Submitted by:

Instrumentation Laboratory Company
113 Hartwell Avenue
Lexington, MA 02421
Phone: 781-861-4467
Fax: 781-861-4464

Contact Person:

Carol Marble, Regulatory Affairs Manager
Phone: 781-861-4467 / Fax: 781-861-4464

Summary Prepared:

August 10, 2000

Name of the Device:

Coaliza Protein S-Free

Classification Name(s):

864.7290	Factor Deficiency Test	Class II
81GGP	Test, Qualitative and Quantitative Factor Deficient	

Identification of predicate device(s):

K983914	REEADS® Monoclonal Free Protein S Antigen Test Kit

Description of the device/intended use(s):

Coaliza Protein S-Free is an *in vitro* diagnostic enzyme-linked ligandsorbent assay for the quantitative determination of free protein S antigen in human citrated plasma. The method principle is based on the high affinity of protein S for C4b Binding Protein (C4BP).

Statement of Technological Characteristics of the Device Compared to Predicate Device:

Coaliza Protein S-Free is substantially equivalent to the commercially available predicate device (REAADS Monoclonal Free Protein S Antigen Test Kit) in performance and intended use.

Section 3
510(k) Summary for Coaliza Protein S-Free (Cont.)
(Summary of Safety and Effectiveness)

Summary of Performance Data:

Method Comparison

Method comparison studies were performed on three different lots of Coaliza Protein S-Free versus the predicate device (REAADS Monoclonal Free Protein S Antigen Test Kit) using a total of 106 citrated plasma samples with free protein S antigen levels ranging from 0.097 to 1.48 IU/ml (9.7 to 148.1% FPS). The slopes and correlation coefficients for the three lots shown in the table below indicate that the tests are statistically similar.

Coaliza Lot 1 vs. Predicate		Coaliza Lot 2 vs. Predicate		Coaliza Lot 3 vs. Predicate	
Slope	**r**	**Slope**	**r**	**Slope**	**r**
0.965	0.972	0.957	0.970	0.887	0.967

Precision

Precision studies evaluated the intra-assay and inter-assay variability of the kit by testing two samples (normal and abnormal control plasmas) run in replicates of six twice a day over five days using two different operators (n=120 per control).

	Intra-assay %CV	Inter-assay %CV
Normal Control Plasma		
Mean 0.89 IU/ml (89% FPS)	2.1%	3.7%
Abnormal Control Plasma		
Mean 0.29 IU/ml (29% FPS)	2.7%	3.7%

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 1 3 2000

Ms. Carole Marble
Manager, Regulatory Affairs
Instrumentation Laboratory Company
101 Hartwell Avenue
Lexington, Massachusetts 02421-3125

Re: K002467
Trade Name: Coaliza Protein S-Free
Regulatory Class: II
Product Code: GGP
Dated: August 10, 2000
Received: August 11, 2000

Dear Ms. Marble:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K002467

Device Name: Coaliza Protein S-Free

Indications for Use:

Coaliza Protein S-Free is an *in vitro* diagnostic enzyme-linked ligandsorbent assay for the quantitative determination of free protein S antigen in human citrated plasma. The method principle is based on the high affinity of protein S for C4b Binding Protein (C4BP).

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Peter E Maglin

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K002467

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.019)